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July 6, 2020

VIA ELECTRONIC FILING

The Honorable Colm F. Connolly
United States District Judge
J. Caleb Boggs Federal Building
844 N. King Street
Unit 31, Room 4124
Wilmington, DE 19801-3555

Re: *Par Pharm., Inc. v. Eagle Pharm., Inc.*, C.A. No. 18-823-CFC

Dear Judge Connolly:

This firm, together with Kirkland & Ellis LLP, represents Defendant Eagle Pharmaceuticals, Inc. (“Eagle”) in the above-captioned matter. We write pursuant to the Court’s May 11, 2020 Oral Order (D.I. 182) regarding redactions to Eagle’s June 24, 2020 Letter (“June 24 Letter”) (D.I. 197). Eagle respectfully submits proposed redactions to the June 24 Letter, along with the supporting Declaration of David Pernock (“Pernock Decl.”).¹ So that this cover letter can remain public, the accompanying confidential Pernock Declaration explains the sensitive nature of the confidential information in the June 24 Letter and the harm that Eagle will suffer should that information be disclosed to the public. Pursuant to D. Del. L.R. 7.1.1, the parties met and conferred on the proposed redactions, and Plaintiffs do not oppose Eagle’s proposed redactions.

Eagle’s proposed redactions to the June 24 Letter are tailored to those portions that disclose confidential information regarding the status of Eagle’s Abbreviated New Drug Application (“ANDA”) No. 211538. The information Eagle seeks to redact is not otherwise available to Eagle’s competitors or the public. Pernock Decl. ¶ 6. Specifically, federal regulations require that the U.S. Food and Drug Administration (“FDA”) keep Eagle’s ANDA confidential until the application is

¹ The Pernock Declaration is filed contemporaneously hereto. A version of the June 24 Letter highlighted to show the specific redactions Eagle seeks is attached as Exhibit A to the Pernock Declaration. A redacted version for public docketing is attached as Exhibit B thereto.

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finally approved. *See* 21 C.F.R. § 314.430; Pernock Decl. ¶ 6. Further, Eagle’s business partners that have access to Eagle’s ANDA are under a contractual obligation to keep the application and related information confidential. Pernock Decl. ¶ 6.

The limited information Eagle seeks to redact is the type of competitively sensitive, proprietary information that Eagle safeguards against disclosure. *See* Pernock Decl. ¶¶ 6–7, 13. Courts have also recognized the status of an unapproved ANDA is confidential and should be sealed during litigation to prevent disclosure. *See, e.g., Supernus Pharm., Inc. v. TWi Pharm., Inc.*, Civ. No. 15-369, slip op. at 6 (D.N.J. Sept. 21, 2017) (granting generic’s motion to seal because “the status of its ANDA with the FDA. . . is classically protected from public disclosure.”).

Moreover, as set forth in the accompanying Pernock Declaration, Eagle respectfully submits that public disclosure of the status of Eagle’s ANDA would cause substantial competitive harm to Eagle. *See* Pernock Decl. ¶¶ 8–12; *Littlejohn v. Bic Corp.*, 851 F.2d 673, 678 (3d Cir. 1988) (courts may “deny access to judicial records, for example, where they are sources of business information that might harm a litigant’s competitive standing” (citation omitted)).

Eagle is mindful of the Court’s desire to permit public access to judicial proceedings, including the public’s ability to understand these proceedings. Eagle respectfully submits, however, that the sensitivity of the confidential information set forth in the limited redactions Eagle seeks weighs in favor of redaction, and allowing Eagle to maintain the confidentiality of this information will not affect the public’s ability to understand the proceeding. *See, e.g., Supernus*, slip op. at 8 (“[T]he Court agrees with TWi that there is little to no legitimate public interest in the public disclosure of TWi’s sensitive information, including . . . the confidential status of its ANDA with the FDA.”).

Eagle respectfully requests that the Court permit these redactions to the public version of June 24 Letter (D.I. 197).

Respectfully,

/s/ Bindu A. Palapura

Bindu A. Palapura

cc: Counsel of Record (via electronic mail)